UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,715	06/26/2001	Richard L. Mueller	5756-0013.30	1828

7590 10/20/2008

Glenn M. Seager
C/O Crompton, Seager & Tufte LLC
Suite 800
1221 Nicollet Avenue
Minneapolis, MN 55403-2420

EXAMINER	
STIGELL, THEODORE J	
ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
10/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/891,715	MUELLER ET AL.	
	Examiner	Art Unit	
	THEODORE J. STIGELL	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-46,49 and 51-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-46,49 and 51-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 June 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/18/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The examiner agrees with the applicant's arguments submitted on 6/30/2008 in that the amendments read on the elected species. Therefore, the response is deemed be fully responsive and an action on the merits now follows.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12/18/2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the separate marking effector and therapeutic substance effector must be shown or the feature(s) canceled from the claim(s). Similarly, the "endoscope" must be shown. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate

changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 35-42, 44, 49, 51-52, and 55-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Ellis et al. (6,416,490). See Figures 3 and 5 and the respective portions of the specification. Ellis discloses a device (20) for treating tissue comprising an elongate shaft having a proximal end, a distal end, and a lumen extending between the proximal end and the distal end, at least one injury effector (23) located at the distal end of the elongate shaft, capable of producing an injury at a first tissue location, and having no therapeutic substance delivery capabilities, at least one therapeutic

substance delivery effector (36) located at the distal end of the elongate shaft, capable of delivering a therapeutic substance to a second tissue location, and at least one marking effector (30 can deliver marking agents, see column 4, lines 15-17) located at the distal end of the elongate shaft for creating a position marker at a third tissue location to indicate treated tissue, wherein the marking effector and the therapeutic substance delivery effector are separate from each other (30 and 36 are separate structures), wherein the at least one injury effector and the at least one marking effector are capable of being sequentially actuated by a control structure, wherein at least a portion of the lumen is configured to receive the therapeutic substance, and wherein at least a portion of the at least one injury effector passes through, and is electrically isolated from (by insulators 24 and 26), the portion of the lumen configured to receive the therapeutic substance, and wherein the marking effector and the injury effector are separate from each other.

Claims 35-42, 44-45, 49, and 51-52, and 54-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Negus et al. (6,902,562). Negus discloses a device (12) for treating tissue comprising an elongate shaft having a proximal end, a distal end, and a lumen extending between the proximal end and the distal end, at least one injury effector (14) located at the distal end of the elongate shaft, capable of producing an injury at a first tissue location, and having no therapeutic substance delivery capabilities, at least one therapeutic substance delivery effector (208) located at the distal end of the elongate shaft, capable of delivering a therapeutic substance to a second tissue location, and at least one marking effector (16) located at the distal end of the elongate

shaft for creating a position marker at a third tissue location to indicate treated tissue, wherein the at least one injury effector and the at least one marking effector are capable of being sequentially actuated by a control structure, wherein at least a portion of the lumen is configured to receive the therapeutic substance, and wherein at least a portion of the at least one injury effector passes through, and is electrically isolated from the portion of the lumen configured to receive the therapeutic substance, and wherein the marking effector and the injury effector are separate from each other.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 43 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis et al. (6,416,490) or Negus et al. (6,902,562) in view of Daniel et al. (6,174,307). Ellis and Negus both disclose all of the limitations recited in the independent claim but fail to explicitly teach using an endoscope in their devices.

Daniel discloses a device for use in TMR procedures wherein the device includes an endoscope that provides access for a working device (i.e., drug delivery needle). The combination of elements allows for a direct view of the surgical site while providing a minimally invasive surgery technique. The advantages of such a device would be readily apparent to one of ordinary skill in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the devices of Ellis and Negus with the configuration of Daniel to provide a minimally invasive surgical device that provided direct visualization of the surgical site.

Claims 45 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis et al. (6,416,490). Ellis discloses all of the limitations recited in the independent claim but fails to explicitly teach wherein the injury effector (23) has a greater exposed length than the therapeutic substance delivery effector (36). In Ellis, the therapeutic substance delivery effector seems to have a slightly greater exposed length than the injury effector (see Figure 5). However, the applicant has not disclosed that such a configuration is for any particular purpose or works better than any other configuration and therefore these limitations are deemed to be matters of design choice that fail to patentably distinguish over the prior art of Ellis. One of ordinary skill in the art would recognize that there will be situations wherein the injury effector needs to be greater than the therapeutic effector (i.e., harder tissue will need more exposed injury effector to produce the injury). One of ordinary skill will recognize that such a small change in size does not result in a patentable difference.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Negus et al. (6,902,562). Negus discloses the claimed invention except for disclosing a plurality of therapeutic substance delivery effectors. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a plurality of the therapeutic effectors, since it has been held "...that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co., 193 USPQ 8 (CA7 1977)*."

Response to Arguments

Applicant's arguments filed 3/5/2008 have been fully considered but they are not persuasive.

Ellis et al. (6,416,490)

Applicant's arguments for Ellis are moot in view of the new grounds of rejection presented above.

Negus et al. (6,902,562)

In response to the applicant's argument that Negus does not disclose the limitation of "at least a portion of the at least one injury effector passes through, and is electrically isolated from, the portion of the lumen configured to receive the therapeutic substance.", the examiner respectfully disagrees. Negus discloses that the lumen (lumen of 12) is designed to hold within it the therapeutic catheter (208) and the injury effector (14). Therefore, the lumen of (12) can be interpreted as receiving the therapeutic substance and electrically isolating the injury effector from the portion of the lumen configured to receive the therapeutic substance.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763